PB86-129350

Hazard Evaluation Division Standard Evaluation Procedure Aqueous Photolysis Studies

(U.S.) Environmental Protection Agency
Washington, DC

Jun 85

U.S. Department of Commerce
National Technical Information Service
NTIS

PB86-129350

EPA-540/9-85-014
June 1985

HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

AQUEOUS PHOTOLYSIS STUDIES

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REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB86 129350/AS

4. Title and Subtitle
HAZARD EVALUATION DIVISION, STANDARD EVALUATION PROCEDURE
Aqueous Photolysis Studies

5. Report Date
June 1985

6.

7. Author(s)
Norma K. Whetzel, Samuel M. Creeger

8. Performing Organization Rept. No.
EPA-540/9-85-014

9. Performing Organization Name and Address
U.S. Environmental Protection Agency/OPP/HED/(TS-769C)
401 M Street SW
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9.

13. Type of Report & Period Covered

14.

15. Supplementary Notes
Supplement to Pesticide Assessment Guidelines Subdivision N - Chemistry: Environmental Fate (EPA-540/9-82-021 and NTIS Order Number PB83-153973), October 1982.

16. Abstract (Limit: 200 words)

The Standard Evaluation Procedure for the Aqueous Photolysis Studies is a guidance document primarily intended for Agency reviewers and the regulated industry who evaluate data specified in 40 CFR Part 158.124. The SEP is also intended to provide information to the general public indicating how the Agency evaluates these types of studies. As such, it is designed to supplement Subdivision N of the Pesticide Assessment Guidelines - Chemistry: Environmental Fate.

The SEP for Aqueous Photolysis Studies is only one of a number of SEP's published by the National Technical Information Service as a supplement to Subdivision N of the Pesticide Assessment Guidelines.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

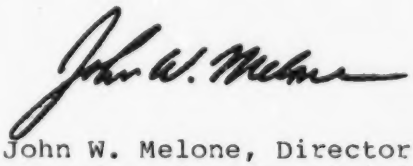
18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
Unclassified and freely available.	Unclassified.	21
	20. Security Class (This Page) Unclassified.	22. Price

(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.



John W. Melone, Director
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AQUEOUS PHOTOLYSIS STUDIES

I. INTRODUCTION

A. Objective

This Standard Evaluation Procedure (SEP) is to be used as an aid for Exposure Assessment Branch data reviewers in their evaluations of aqueous photolysis studies submitted by registrants in support of pesticide registration.

40 CFR Part §158.130[1] requires aqueous photolysis studies to be conducted with each pesticide active ingredient intended for any terrestrial use (except greenhouse and domestic outdoor use), aquatic use, or forestry use, or for any aquatic impact uses involving direct discharges of treated water into outdoor aquatic sites. This study is also required for a manufacturing-use product which may be used to formulate an end-use product for such uses.

B. General Theory

Pesticides can be applied directly to aquatic systems or can enter aquatic systems via leaching or runoff after terrestrial application. Upon entering aquatic systems, pesticides can undergo photolytic transformation by sunlight (photolysis). Therefore, data on rates of photolysis in water of the parent pesticide and its photodegradates are needed to establish the importance of this transformation process and the persistence characteristics of photoproducts formed.

A brief discussion of some basic photochemistry concepts is contained in Appendix A. The reviewer is referred to physical chemistry and photochemistry texts and many of the papers and books in the attached references for a more complete discussion of theory.

II. THE SUBMITTED STUDY

A. Purpose

The purpose of the study is to determine rates of aqueous photolysis of the pesticide ($t_{1/2}$) and identify photolytic products and rates of formation and decline of these products. The section in the Subdivision N Guidelines[2] which describes this study and provides sample protocol is 161-2.

B. Study Design

The Subdivision N Guidelines[2] and the Data Submission Format Guidelines for Photolysis Studies[3] contain detailed information about what information must be supplied with the aqueous photolysis study and under what conditions the study should be conducted. The registrant's report should contain the stated goal and sufficient information on the test protocol (compound purity and type of compound used; concentration of the compound in solution; detailed description of light conditions; sufficient description of sampling frequency) and the analytical protocol (description of methods used for quantitative and qualitative analyses and reports on the quality control procedures used to ensure the validity of the study).

Specific information that the registrant should include with the study is listed in Appendix B.

III. THE EVALUATION PROCCESS

A. Determine the Need for the Study

For all data submitted as part of a registration action, the reviewer is to first determine whether the data is needed in support of the proposed use. If an initial look at the study reveals that the data supplied is not relevant and not needed to support the proposed registration action, then the reviewer should only mention in the review that the particular study was submitted but was not reviewed and why.

B. Read the Report

Read the aqueous photolysis report keeping the following broad issues in mind: (1) Are the goals appropriate, (2) Was the study conducted in a scientifically sound manner to meet those goals, (3) Were the experimental design, test substance and experimental procedures adequately described and, (4) Are there data gaps that impede the review process or invalidate the study?

C. Prepare the Data Evaluation

The reviewer should now prepare the Data Evaluation Record (DER) according to the Standard Format for Preparation of Environmental Fate Reviews. Appendices B-D should be used in this process.

1. Write the Technical Evaluation

In the DER of the study, the reviewer is to record (1) whether the submitted study reliably defines the rate of aqueous photolysis

of the a.i., and (2) the identity of the photoproducts present at > 10%. The identity of photoproducts present at < 10% of the initial dose may be needed in cases where high concentrations of parent compound are applied to or may be found in aqueous systems.

2. Determine Study Acceptability

From the scientific point of view, the reviewer now determines if the study satisfies the aqueous photolysis data requirement in light of the proposed use.

3. Make Regulatory Determination

Based on the scientific results of the aqueous photolysis study, the reviewer now makes a statement on the impact the photolytic fate of the pesticide will have on the environment, such as persistence in water.

4. Determine Need for Deferral/Referral to Other HED Branches

If the parent compound or any of its degradation products are found to be stable to aqueous photolysis, then it may impact on ground water and/or aquatic organisms. Referral of this information should be made to the appropriate branches in HED after review of the other environmental fate studies.

APPENDIX A

GENERAL THEORY AND REFERENCES FOR EVALUATING AQUEOUS PHOTOLYSIS STUDIES

Photolysis is the interaction of a compound with light in which bonds are broken as a result of the transfer of energy to those bonds.[4] While photolysis is viewed as a degradation process, compounds are not necessarily broken down into constituent parts or simpler compounds. Sunlight can transform the original compound into compounds of similar or even greater structural complexity.[5]

The energy transfer can occur in two ways: (1) directly from the light to the affected compound or (2) indirectly from the light to another compound which then transfers the light energy to the affected compound. The latter process is called sensitized energy transfer.[6]

The basic law of photochemistry states that only light which is absorbed can effect chemical change in a system.[7] The relationship of wavelength to the energy of one photon of radiation is derived from the following equations:

$$E = h\nu \; ; \quad \nu = c/\lambda \; ; \text{ therefore, } E = hc/\lambda$$

where E is the energy in ergs, ν is the frequency in time^{-1}, h is Planck's constant (6.6×10^{-27} erg sec), c is the velocity of the radiation in cm time^{-1} and λ is the wavelength in cm.[4] Thus, the energy at any frequency can be calculated. Using this equation and comparing typical bond dissociation energies with energy levels associated with molecular transitions in different absorption regions, one finds that only electronic transitions from the UV/visible absorption region are energetic enough to lead to chemical reactions.[8] Since "the stratospheric ozone layer effectively prevents UV irradiation of less than 290 nm from reaching the ecosphere,"[8] the absorption region of interest is narrowed to 290-750 nm.[8]

APPENDIX B

INFORMATION SUBMITTED AS PART OF THE AQUEOUS PHOTOLYSIS STUDY

1. The goals of the experiment.
2. Chemical name, common name, trade name, company designations and structures of both the active ingredient (a.i.) and the photolytic products.
3. Water solubility of the a.i..
4. Source and purity of the a.i..
5. Site of radiolabeling (if applicable).
6. Source and purity of the water.
7. Concentration of a.i. at which the study was conducted.
8. Buffer solution(s) used and how it (they) was (were) prepared.
9. Description of experimental equipment (glassware, analytical equipment, artificial lighting arrangement, etc.).
10. Complete description of the analytical procedure (See Appendix D.).
11. Test conditions (temperature, sterility, pH and darkness).
12. Method for adding the a.i. to the buffer solution.
13. Means of sterilization.
14. Means and technique of sampling and handling of sample.
15. Storage of samples (if applicable).
16. Rate of photolysis of the a.i. and the identity of the photolysis products.
17. Cosolvent (if applicable).
18. For artificial light sources: the nature of the light source, its emission wavelength spectrum and intensity and their relationship to that of natural sunlight.
19. For sunlight sources: the latitude, time of year, atmospheric cover, and other major variables affecting incident light.

20. Method of calibrating and measuring the intensity of incident light.

21. The intensity of incident light and time of exposure with duration of dark and light periods.

22. Quality assurance. A complete description of the measures taken to insure the integrity of the study. This section should include: logbooks and/or record-keeping procedures; representative instrument printouts (chromatograms, spectra, etc.); sample coding; use of replicate samples and control blanks; use of written and validated analytical methodology, including modification(s) made; skilled laboratory personnel; well-equipped laboratory facility; use of high quality glassware, solvents, and test compounds; minimal contamination; calibration and maintenance of instruments; good laboratory practices in handling the test substance(s).

23. Contact for questions from the reviewer.

24. Raw data, sample chromatograms and sample calculations on how the photolysis rates were derived and how the photolysis products were identified.

25. Special problems with the study such as adhesion of a.i. to the test equipment, a.i. insoluble in water, emulsion formed, buffer catalysis, etc..

APPENDIX C

CONSIDERATIONS IN REVIEWING AQUEOUS PHOTOLYSIS STUDIES

1. Were the name and structure of the parent and photoproduct(s) provided?

2. Was the temperature controlled at 25 $\pm$ 1°C and monitored?

3. Was the cosolvent $\leq$ 1% by volume?

4. Was the cosolvent determined to be a non-photosensitizer?

5. Was the appropriate buffer type used?

6. Was the buffer at the appropriate concentration?

7. Was the starting concentration high enough to permit the isolation and identification of photoproducts formed?

8. Were precautions taken to minimize losses through volatilization?

9. Were appropriate traps utilized to contain volatile products for analysis?

10. Was a test made for the possible binding of the test compound to the surface of the reaction vessel?

11. Was the pH of greatest hydrolytic stability in the pH range of 5-9 used as determined by the hydrolysis study?

12. For compounds which are not hydrolytically stable in the pH range of 5-9, was the rate study done at pHs 5, 7 and 9 for compounds which reversibly ionize or protonate within the pH range of 5-9?

13. Was the study done under sterile conditions to minimize biological degradation?

14. Was the radiolabel in a stable portion of the compound?

15. Were sufficient samples taken and at appropriate times during the study? Were adequate replicates made?

16. Did the study continue through at least 1 half-life or 30 days, whichever came first?

17. Were there controls, prepared and maintained as for the other samples, except that they were kept in the dark?

18. For sunlight as the source, were the following given:

    - a record of the intensity of incident sunlight?
    - time of exposure?
    - latitude?
    - time of year?
    - atmospheric cover?
    - other major variables which affect incident light?

19. For artificial light as the source, were the following given:

    - description of the source?
    - intensity?
    - wavelength distribution? (emission spectrum)
    - time of exposure?
    - the relationship of the light intensity employed to that of natural sunlight?

20. Were filters used in the experimental apparatus to remove wavelengths below 290 nm?

21. Were photoproducts produced in >10% yield identified?

22. Was there a good material balance?

23. Was a half-life estimate made for the parent compound?

24. Was there an impurity in the a.i. that would interfere with the analytical method?

25. Was the analytical method adequately described? Were statistics verifiable?

26. Were raw data and samples of analytical data sheets, chromatograms, calculations, etc., given?

27. Were control samples, prepared and handled the same as the pesticide treated study samples, run in each experiment?

APPENDIX D

TEST PARAMETERS INFLUENCING AQUEOUS PHOTOLYSIS

1. Experimental Design

From the considerations of Appendix C, the reviewer must draw some conclusions about the influence of the experimental design on the validity of the study for the proposed use. Some questions the reviewer should answer are:

1. Was sunlight, if used, representative of the area of proposed use?

2. Did the emission wavelength spectrum of the artificial source, if used, simulate that of natural sunlight?

3. Was the pattern of light and dark given and was it reasonable for the proposed use pattern (i.e., 12 hours of light/12 hours of dark per day; 16 hours of light/8 hours of dark per day, etc.)?

4. Was the relationship of the intensity of the artificial sunlight used appropriate to that of natural sunlight in the area and for the time of the planned use?

5. Was a suitable method used for measuring the intensity of incident light?

Other aspects of the experimental design which influence the aqueous photolysis study are concentration, sterile conditions, and competing natural processes.

Since experience has shown that photolysis proceeds by first-order or pseudo first-order kinetics at high doses,[9] the starting concentration of the pesticide in the aqueous photolysis study need not be at the expected low environmental levels but may be at a high enough level to define the reaction kinetics and permit the isolation and identification of the photoproducts formed.

The study should be conducted under sterile conditions to eliminate biological metabolism and at a pH between 5 and 9 of maximum hydrolytic stability to minimize hydrolysis. In the case of compounds which reversibly ionize or protonate within the pH range of environmental concern (pH 5-9), aqueous photolysis rate determination studies should be conducted at pHs 5, 7, and 9.

Photolysis competes in nature with both biological metabolism and hydrolysis.[4] Under actual environmental conditions, one process may predominate over the others. The reviewer must be aware that photoproducts produced in a laboratory aqueous photolysis study may not be found in water in the environment[4] if hydrolysis or metabolism is the major pathway of environmental degradation.

2. Buffers

See the discussion of buffers in the hydrolysis SEP for consideration of choice and concentration.

Cosolvents have been used in aqueous photolysis studies to increase the solubility of pesticides with low water solubilities.[10, 11] Preferably, cosolvents should be used only when absolutely necessary to solubilize water-insoluble pesticides bringing them to a starting concentration sufficient to allow the study to proceed. The cosolvent should not exceed 1% by volume and should not act as a photosensitizer. Cosolvents should not be photosensitizers, nor should they absorb light in the range of concern. Methanol and acetonitrile are the preferable cosolvents for aqueous photolysis.[12]

3. Nature of Light and Factors Affecting the Incident Light

The reviewer should be aware that photolysis rate constants and half-lives in the environment will vary with weather conditions and with time of year[6] as well as with latitude and atmospheric conditions[7] (See Figures 1 and 2 showing the effects of season and latitude on the intensity of short and long wavelength sunlight.[7]). Therefore, when artificial light is used, the spectra should be similar to that of natural sunlight at a typical use site. The inclusion of the absorption spectrum of the test compound can aid the reviewer in deciding if the appropriate light source has been used.

Various kinds of glass absorb and transmit different wavelengths.[8] Therefore, the kind of glass (both in vessels and filters) should be specified and its transmissibility considered in evaluating the adequacy of the study. Also, the reference which gives the transmissibility of the glass should be current, as the glass manufacturing processes have changed with a concomitant change in transmissibility of glass batches.[13] Quartz is the glass of choice;[12] borosilicate glass is acceptable to some[12] but not others;[12a] therefore, its transmissibility should be defined. The reviewer should also be aware that borosilicate glass varies with manufacturer.[12]

4. Radiolabeling

Use of radiolabeled pesticide provides easier accountability of material balance as well as easier identification of degradation products than use of non-radiolabeled starting material. If radiolabeling is done, it should be in a stable portion of the molecule. For a more complete discussion of the use of radiolabeling in studies submitted to EAB see the Standard Evaluation Procedure for Hydrolysis.

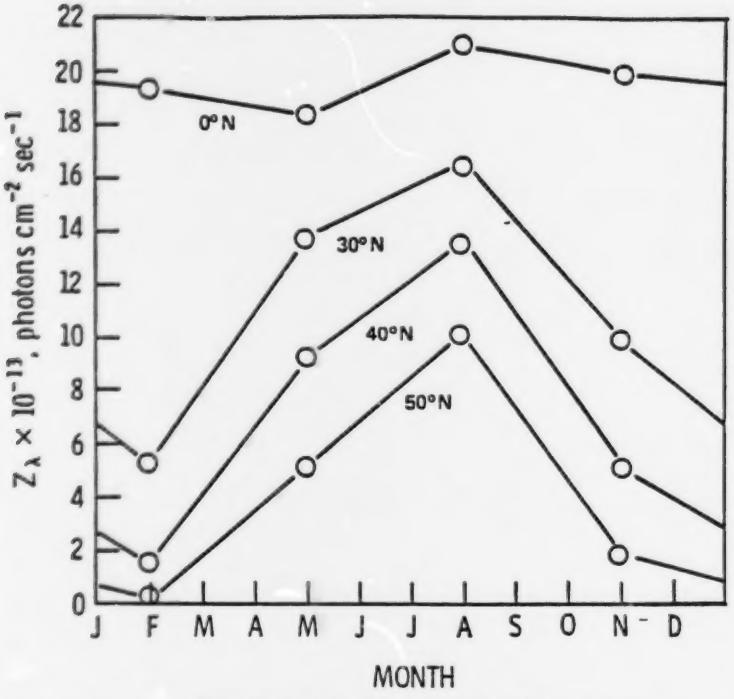

Fig. 1 Dependence of short-wavelength solar uv irradiance ppon season and latitude

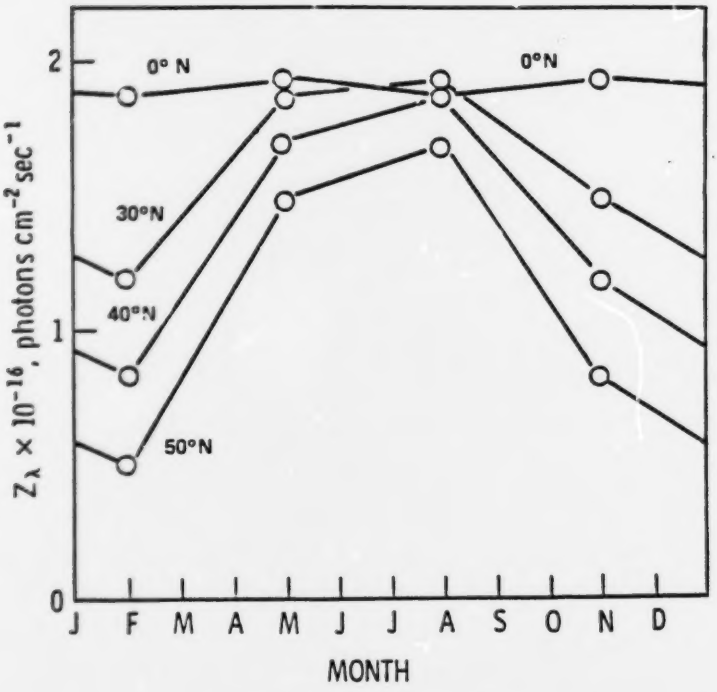

Fig. 2 Dependence of long-wavelength solar uv irradiance upon season and latitude

5. Mass Balance

All of the radioactivity used in the experiment must be accounted for to ensure that all the photolysis products have been detected and that the fate of all of the starting material is understood. The reviewer must be able to ascertain that the data on the mass balance are adequate. Generally the study results should account for $\geq$ 95% of the starting mass (as represented by the radioactivity when employed). An explanation should accompany any study which is not able to account for at least 95% of the starting mass.

Care must be taken to ensure that no products are lost due to volatilization. Therefore, traps should be used to monitor the possible production of volatile photolysis products. Also, consider possible binding of the pesticide to the surface of the test equipment which can occur unexpectedly, resulting in an unaccountable loss of mass and possible invalidation of the study.

6. Photosensitization

Although the Subdivision N Guidelines[1] provide for a "supplemental rate and photoproduct identification study" which "may also be carried out in the presence of a photosensitizer," the reviewer should request a photosensitized study for each pesticide, since most, if not all, natural waters contain photosensitizers.[14, 15, 16] Any pesticide reaching natural water is likely to encounter a photosensitizer.

7. Duration/Sampling

A study duration of 30 days is usually sufficient to establish whether a compound will be resistant to photolysis. As a practical matter, if less than about 10% of the pesticide photolyzes within 30 days, the pesticide will be considered photolytically stable in water.

Generally, aqueous photolysis studies of 30 days duration will suffice, since dilution in the environment is likely to reduce any concerns by that time. However, in cases in which dilution is not likely to occur at a significant rate; e.g., ditch bank empoundments, ponds, etc., then consideration must be given to experiments of longer duration.

Samples should be taken for analysis at four or more time intervals with at least one sample made after one half-life or at 30 days of natural sunlight (about 12 hours of light/12 hours of dark per day) whichever comes first. The number and timing of the samples will depend on the half-life of the compound and should define the pattern of decline of the pesticide undergoing photolysis.

8. Analytical Method

A detailed description of the analyses used to determine the parent and photoproducts should be given. The following information should be included:

1. Name (and signature), title, organization, address, and telephone number of the person(s) responsible for the planning/supervision/monitoring and laboratory procedures/analyses.

2. Analytical method(s) title/designation/date.

3. Source of analytical method(s) [e.g., Pesticide Analytical Manual (PAM), Vol. II, scientific literature, Company reports, other].

4. Principles of the analytical procedure [describe].

5. Non-Confidential Business Information (non-CBI) copy of the analytical method(s) detailing in step-wise fashion the procedures (extraction, clean-up, derivatization, determination, calculation of the magnitude of the compound(s)).

6. Reagents or procedural steps requiring special precautions [to avoid safety and health hazards, explain].

7. Identification of the chemical species determined.

8. Modifications, if any, to the analytical method(s) [detail].

9. Extraction efficiency [if pertinent].

10. Instrumentation [make/model; type/specificity of detector(s); column(s) (packing materials, size); carrier gas(es); flow rate(s); temperature(s); voltage; limit of detection and sensitivity; calibration procedures; etc.].

11. Interference(s), if any [describe].

12. Confirmatory techniques [e.g., different column packing(s) or detector(s), etc.].

13. Sample identification [coding and labeling information; should be the same as - or cross-referenced to - the sample coding/labeling assigned at harvest].

14. Results [raw data; laboratory worksheets; step-wise calculation of levels; dilution factors; peak heights/areas; method correction factor(s) applied (e.g., storage stability and method validation recovery values); formula(e)/standard curve(s)

used; amount found of total applied, and of individual component(s) (i.e., photoproducts); range of values; representative chromatograms, spectra, etc. (as applicable) from control and treated samples; etc.].

15. Statistical treatment(s) [describe test(s) applied to the raw data].

16. Quality assurance [control measures/precautions followed to ensure the fidelity of determinations, including logbooks and record-keeping procedures; representative instrument print-outs (chromatograms, spectra, etc.); sample coding; use of replicate samples and control blanks; use of written and validated analytical methodology for analyses, including modification(s) made; skilled laboratory personnel; well-equipped laboratory facility; use of high-quality glassware, solvents, and test compound(s); minimize contamination; calibration and maintenance of instrumentation; good laboratory practices.

17. Time required for analysis [to carry a sample completely through the analytical procedure, including the determinative step].

18. Other [any and all additional information the registrant considers appropriate and relevant to provide a complete and thorough description of residue analytical methodology and the means of calculating the residue results].

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